

U.S.S.N. 09/662,927

Filed: September 15, 2000

**AMENDMENT AND RESPONSE TO FIRST (NON-FINAL) OFFICE ACTION**

**Remarks**

Reconsideration in view of the foregoing amendments and the following remarks is respectfully requested.

**Response to Restriction Requirement**

Applicant confirms the election of March 22, 2002, without traverse, to prosecute claims 1-9, 19-23, 27, 28 and 30-33, corresponding to Group I. Claims 10-18, 24-26 and 29, corresponding to Groups II – IX, are cancelled without prejudice. In making this cancellation without prejudice, applicant reserves all rights in these claims to file Divisional and/or Continuation Patent Applications.

**Amendments to the Claims**

Claims 1 and 33 have been amended to recite at least one actuator in the device for causing a configurational change in the device in response to a sensed condition. Support for these amendments is found at numerous locations in the specification, for example, at page 3, line 31 to page 4, line 14.

Claim 3 has been amended. Support for this amendment is in the Specification, for example, at page 5, lines 3-10, and page 10, line 30 to page 11, line 3.

Claims 7, 14 and 30 have been amended for formalities, so as to have proper antecedents in claim 1, from which they depend. Similarly, claim 31 has been amended for formalities, so as to have a proper antecedent in claim 30, from which it depends.

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Claim 8 has been amended. Support for this amendment is found in the specification, for example, at page 11, lines 5-8.

Claim 9 has been amended. Support for this amendment is found in the specification, for example, at page 6, line 30 to page 7, line 10.

Claims 22 and 23 have been amended for formalities, and in particular, proper dependency on claim 1, as claim 21 has been cancelled.

Claims 27 and 28 have been amended. Support for the amendments to these claims is found in the Specification, for example, at page 7, lines 11-19.

**Rejections Under 35 USC 112, Second Paragraph**

Claims 27 and 28 were rejected under 35 USC 112, second paragraph, as indefinite. This rejection is respectfully traversed to the extent that it is applied to the claims as amended.

Claims 27 and 28 have been amended. It is respectfully asserted that these amendments render these claims definite and overcome the rejection, whereby claims 27 and 28 are proper under 35 USC 112, second paragraph.

**Rejections Under 35 USC 101**

Claims 3, 27 and 28 were rejected under 35 USC 101. Claims 27 and 28 were rejected as improperly defining a process while claim 3 was rejected as directed to non-statutory subject matter. These rejections are respectfully traversed to the extent that they are applied to the claims as amended.

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Claims 3, 27 and 28 have been amended. Claim 3 has been amended such that the patient is not part of the claim. Claims 27 and 28 have been amended to define the sensor structurally as capable of performing the recited functions. It is respectfully asserted that these amended claims overcome the rejection, whereby claims 3, 27 and 28 are proper under 35 USC 101.

**Rejections Under 35 USC 102**

Claims 1-9, 19, 21-23, 30 and 33, were rejected under 35 USC 102(b) as being anticipated by Bowers (U.S. Patent No. 4,399,821) and under 35 USC 102(e) as being anticipated by Miesel, et al. (U.S. Patent No. 6,248,080) (Miesel). These rejections are respectfully traversed to the extent that they are applied to the claims as amended.

Initially, claim 21 has been cancelled, whereby the rejections of this claim are now moot.

Claims 1 and 33 have been amended to additionally recite at least one actuator in the device for causing a configurational change in the device in response to a sensed condition.

Bowers teaches an implantable device, designed to sense a condition and stimulate a muscular twitch or other response in the animal, allowing it to be distinguished from other animals. The implantable device lacks any actuation mechanism for changing the configuration of the device.

Based on the above, Bowers fails to show the structure recited in claims 1 and 33. Accordingly, it is respectfully asserted that claims 1 and 33 are not anticipated by Bowers under 35 USC 102(b), whereby withdrawal of these rejections is respectfully requested.

Miesel discloses an implantable medical device, from which an intercranial lead extends. The intercranial lead can include pressure and temperature sensors. The implanted

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device is designed for subcutaneous implantation. The implantable medical device includes various electronic components for signal processing, but fails to have any structure that would actuate it so as to change its configuration.

Based on the above, Miesel fails to show the structure recited in claims 1 and 33. Accordingly, it is respectfully asserted that claims 1 and 33 are not anticipated by Meisel under 35 USC 102(e), whereby withdrawal of these rejections is respectfully requested.

Since claim 1 is not anticipated by Bowers under 35 USC 102(b) or by Meisel under 35 USC 102(e), claims 2-9, 19, 22, 23 and 30, dependent thereon, are also allowable over Bowers and Meisel for the same reasons. These claims further distinguish the invention over Bowers and Meisel.

Claims 1, 4, 8, 9 and 20, were rejected under 35 USC 102(e) as being anticipated by Darrow, et al. (U.S. Patent No. 6,201,980) (Darrow).

Claim 20 has been cancelled, whereby the rejection thereof is now moot.

Claim 1 has been discussed above. That discussion is applicable here.

Darrow is directed to an analyte sensor, with a bellows shaped cavity filled with an expandable analyte sensitive polymer. The cavity is within a sealed transducer package, whose volume remains constant. Accordingly, although the analyte sensitive polymer expands, its expansion does not cause the transducer package to change in volume, whereby the sensor does not undergo a configuration change.

Based on the discussion above, Darrow fails to show the structure recited in claim 1. Accordingly, it is respectfully asserted that claim 1 is not anticipated by Darrow under 35 USC

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102(e), whereby withdrawal of this rejection is respectfully requested. This rejection is respectfully traversed to the extent that it is applied to the claims as amended.

Since claim 1 is not anticipated by Darrow under 35 USC 102(e), claims 4, 8, and 9, dependent thereon, are also allowable over Darrow for the same reasons. These claims further distinguish the invention over Darrow.

**Rejections Under 35 USC 103(a)**

Claims 27 and 28 were rejected under 35 USC 103(a) as obvious over Bowers (U.S. Patent No. 4,399,821) in view of Winston, et al. (U.S. Patent No. 5,411,551). This rejection is respectfully traversed to the extent that it is applied to the claims as amended.

Claims 27 and 28 are dependent on claim 1, that has been discussed above. That discussion is applicable here.

Bowers has also been discussed above. That discussion is also applicable here.

Winston, cited to teach blood glucose sensors, fails to cure the deficiencies associated with Bowers, as it also fails to show structure for actuating and changing the sensor configuration.

Since claim 1 is nonobvious under 35 USC 103(a) in view of Bowers and Winston, claims 27 and 28, dependent thereon are also allowable over the cited art for the same reasons. These claims additionally distinguish the invention over the cited art.

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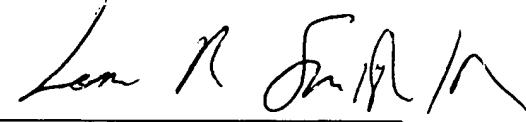
Conclusion

The applicant also notes the Examiner's citations of Bardy (U.S. Patent No. 6,312,378), and Ellinwood, Jr. (U.S. Patent No. 4,146,029) to complete the record.

Should the Examiner have any questions, or comments as to the form, content or entry of this paper, the undersigned can be contacted , preferably by telephone, at the address below.

Allowance of pending claims 1-9, 19, 22, 23, 27, 28 and 30-33, is respectfully solicited.

Respectfully submitted,



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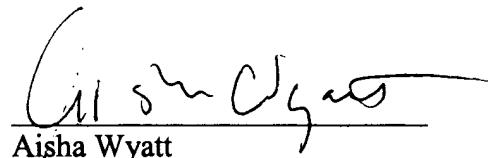
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**Certificate of Mailing Under 37 C.F.R. § 1.8(a)**

I hereby certify that this paper, along with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on the date shown below with sufficient postage as first-class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.



Aisha Wyatt

Date: July 17, 2002

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**MARKED UP VERSION OF AMENDED CLAIMS**

**Marked Up Version of Amended Claims**

**Pursuant to 37 C.F.R. § 1.121**

1. (Once Amended). A system for monitoring and responding to the environment of an implanted device comprising:

one or more sensors configured for monitoring data relating to variables selected from the group consisting of electrical, magnetic, mechanical, fluid flow, chemical, and thermal properties in the device or its environment in a patient, and

[monitoring and/or actuating means] at least one actuator configured for implementing a response to the monitored data in the device by causing a configurational change in the device.

3. (Once Amended). The system of claim 2 wherein the data storage means is configured to be placeable on the device or contiguous to the device or within or on the body of the patient.

7. (Once Amended). The system of claim 1 comprising an external input connected through loops to effectuate change in the device from [an] the at least one actuator [means].

8. (Once Amended). The system of claim 1 [wherein the] additionally comprising monitoring means [is] configured for positioning external to the patient.

9. (Once Amended). The system of claim 1 wherein the sensor is configured to detect [detects] changes in pH, temperature, ion concentration, or analyte concentration.



**MARKED UP VERSION OF AMENDED CLAIMS**

19. (Once Amended). The system of claim 1 comprising transmitting and receiving means to the [sensor] one or more sensors.

22. (Once Amended). The [sensor] system of claim 1 [21] further comprising means for remotely accessing the data.

23. (Once Amended). The [sensor] system of claim 1 [21] wherein [the] at least one sensor is connected to means for transmitting or receiving data from a computer or phone communication means.

27. (Once Amended). The [sensor] system of claim 1 [or 21] wherein [the] at least one sensor [can be used] is configured to measure fouling of the device or at least one sensor over time.

28. (Once Amended). The [sensor] system of claim 1 [or 21], wherein [the] at least one sensor [can] is configured to measure protein deposition or formation of a bacterial film on a biliary stent, increase in calcification of a urinary stent, and neointimal thickening of an arterial stent, resulting in an increase in thickness, mass and wall shear.

30. (Once Amended). The system of claim 1 comprising:

(a) one or more sensors for monitoring the general environment of the [implant] implanted device;

**MARKED UP VERSION OF AMENDED CLAIMS**

(b) monitoring means; and

(c) [actuating means for responding to the environment; wherein] the one or more sensors configured for communicating [communicate] information to the monitoring means and to each other, and [wherein the sensors communicate] configured for communicating commands to the actuator [actuating means].

31. (Once Amended). The system of claim 30 wherein the one or more sensors communicate information to a computer transmitting the information to another computer via the internet.

33. (Once Amended). An implantable device comprising:

one or more sensors configured for monitoring at least one condition;

at least one actuator configured for implementing a response to the monitored

condition in the device by causing a configurational change in the device; and

the one or more sensors and the at least one actuator configured for control by at

least one apparatus [interacting with] external [monitoring and/or activating means and a

computer] to the implantable device.